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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/492,764 | 01/27/2000 | Richard Jove | 114205.1101 | 1344 |

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| EXAMINER | |
|---|---|
| RAWLINGS, STEPHEN L | |
| ART UNIT | PAPER NUMBER |
| 1642 | 13 |

DATE MAILED: 07/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/492,764 | Applicant(s) JOVE ET AL. | |
|---|---|---|---|
| | Examiner Stephen L. Rawlings, Ph.D. | Art Unit 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 May 2002* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election facsimile cover sheet* .

## DETAILED ACTION

1. Claims 1-18 are pending in the application and are currently subject to a restriction and election requirement.

### *Election/Restrictions*

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an inhibitor of STAT dimerization, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group II. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an inhibitor of Jak, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group III. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an inhibitor of Src, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group IV. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an inhibitor of BCR-Abl, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group V. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of SH2-pY interaction, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group VI. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an a dominant negative STAT protein, classified in class 514, subclass 2.

Group VII. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of the DNA binding activity of STAT, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group VIII. Claims 1-5 and 12-14, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient a tyrphostin inhibitor, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group IX. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of transactivation of a gene by STAT, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group X. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of IL-6 receptor activation, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XI. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of a cytokine, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XII. Claims 1-5, insofar as the claims are drawn to a method for inhibiting the growth of cancer cells in a patient, wherein said method comprises administering to said patient an antagonist of a growth factor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XIII. Claim 6, drawn to a method for inhibiting neoplastic transformation of a cell of a subject, wherein said method comprises administering to said subject an antagonist of STAT3 activation, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XIV. Claim 7, drawn to a method for increasing the efficiency of a chemotherapeutic agent, wherein said method comprises administering to a patient an antagonist of STAT3 activation, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XV. Claim 8, drawn to a method for increasing the efficiency of radiation therapy, wherein said method comprises administering to a patient an antagonist

of STAT3 activation, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XVI. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an inhibitor of STAT dimerization and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group XVII. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an inhibitor of STAT tyrosine phosphorylation and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group XVIII. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of SH2-pY binding and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XIX. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of the DNA binding activity of STAT and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XX. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with a tyrphostin inhibitor and electroporating said tumor, which

cannot be classified because the chemical and biologic nature of said inhibitor is not disclosed.

Group XXI. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of transactivation of a gene by STAT and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XXII. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of IL-6 receptor activation and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XXIII. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of a cytokine and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XXIV. Claim 9, insofar as the claim is drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with an antagonist of a growth factor and electroporating said tumor, which cannot be classified because the chemical and biologic nature of said antagonist is not disclosed.

Group XXV. Claims 10 and 11, drawn to a method for inducing apoptosis in the cells of a solid tumor, wherein said method comprises contacting said tumor with

a DNA construct comprising a polynucleotide sequence encoding a dominant-negative variant of STAT3, classified in class 514, subclass 44.

Group XXVI. Claims 15-17, drawn to a cell line, classified in class 435, subclass 326.

Group XXVII. Claim 18, drawn to a method for screening compounds, classified in class 435, subclass 8.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions in groups I-XXV and XXVII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success. Therefore, each claimed method is a distinct invention.

The inventions in groups XXVI and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the cell line can be used in a materially different process of using that product, such as studying signal transduction pathways that regulate the activity of the STAT3-responsive promoter.

The inventions in group XXVI and groups I-XXV are not at all related because the products of group XXVI are not specifically used in any of the steps of the claimed method in groups I-XXV.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their

different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Claim 12 is generic to a plurality of patentably distinct species of invention wherein said tyrphostin inhibitor is one of the inhibitors selected from the group consisting of (a) AG490, (b) AG17, (c) AG213, (d) AG18, (e) AG82, (f) AG494, (g) AG825, (h) AG879, (i) AG1112, (j) AG1296, (k) AG1478, (l) AG126, (m) RG13022, (n) RG14620, and (o) AG555. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

(703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

slr
July 1, 2002

# RESTRICTION ELECTION FACSIMILE TRANSMISSION

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